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(ii) A DSMO that participated in the review and analysis of the request for the proposed modification, or the proposed new standard.

(4) Expedited process to address content needs identified within the industry, if appropriate.

(5) Submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS).

§ 162.915 Trading partner agreements.

A covered entity must not enter into a trading partner agreement that would do any of the following:

(a) Change the definition, data condition, or use of a data element or segment in a standard or operating rule, except where necessary to implement State or Federal law, or to protect against fraud and abuse.

(b) Add any data elements or segments to the maximum defined data set.

(c) Use any code or data elements that are either marked “not used” in the standard’s implementation specification or are not in the standard’s implementation specification(s).

(d) Change the meaning or intent of the standard’s implementation specification(s).

[65 FR 50367, Aug. 17, 2000, as amended at 76 FR 40495, July 8, 2011]

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 714-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. The materials are also available for inspection by the public at the Centers for Medicare &

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Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244. For more information on the availability on the materials at CMS, call (410) 786-6597. The materials are also available from the sources listed below.

(a) *ASC X12N specifications and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3*. The implementation specifications for the ASC X12N and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (and accompanying Errata or Type 1 Errata) may be obtained from the ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970-4480; and FAX (703) 970-4488. They are also available through the internet at <http://www.X12.org>. A fee is charged for all implementation specifications, including Technical Reports Type 3. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1, as referenced in § 162.1102 and § 162.1802.

(2) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1, as referenced in § 162.1102 and § 162.1802.

(3) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as referenced in § 162.1102 and § 162.1802.

(4) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington

Publishing Company, 004010X091A1 as referenced in § 162.1602.

(5) ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1, as referenced in § 162.1502.

(6) The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1, as referenced in § 162.1702.

(7) The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1, as referenced in § 162.1302.

(8) The ASC X12N-276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1, as referenced in § 162.1402.

(9) The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, as referenced in § 162.1202.

(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim Dental (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1, as referenced in § 162.1102 and § 162.1802.

(11) The ASC X12 Standards for Electronic Data Interchange Technical Re-

port Type 3—Health Care Claim: Professional (837), May 2006, ASC X12, 005010X222, as referenced in § 162.1102 and § 162.1802.

(12) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12/N005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1, as referenced in § 162.1102 and § 162.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221, as referenced in § 162.1602.

(14) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in § 162.1502.

(15) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218, as referenced in § 162.1702.

(16) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1, as referenced in § 162.1302.

(17) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1, as referenced in § 162.1402.

(18) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility

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Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, as referenced in §162.1202.

(b) *Retail pharmacy specifications and Medicaid subrogation implementation guides.* The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for the Medicaid pharmacy subrogation transaction may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477-1000; FAX (480) 767-1042. They are also available through the Internet at <http://www.ncpdp.org>. A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The Telecommunication Standard Implementation Guide Version 5, Release 1 (Version 5.1), September 1999, National Council for Prescription Drug Programs, as referenced in §162.1102, §162.1202, §162.1302, §162.1602, and §162.1802.

(2) The Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, National Council for Prescription Drug Programs, as referenced in §162.1102, §162.1202, §162.1302, and §162.1802.

(3) The National Council for Prescription Drug Programs (NCPDP) equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 0, February 1, 1996, as referenced in §162.1102, §162.1202, §162.1602, and §162.1802.

(4) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, as referenced in §162.1102, §162.1202, §162.1302, and §162.1802.

(5) The Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006, National Council for Prescription Drug Programs, as referenced in §162.1102, §162.1202, §162.1302, and §162.1802.

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(6) The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in §162.1902.

(c) Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE), 601 Pennsylvania Avenue, NW. South Building, Suite 500 Washington, DC 20004; Telephone (202) 861-1492; Fax (202) 861- 1454; E-mail info@CAQH.org; and Internet at <http://www.caqh.org/benefits.php>.

(1) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase I Policies and Operating Rules, Approved April 2006, v5010 Update March 2011.

(i) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, as referenced in §162.1203.

(ii) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011, as referenced in §162.1203.

(iii) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011, as referenced in §162.1203.

(iv) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011, as referenced in §162.1203.

(v) Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011, as referenced in §162.1203.

(vi) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011, as referenced in §162.1203.

(2) ACME Health Plan, HIPAA Transaction Standard Companion Guide, Refers to the Implementation Guides Based on ASC X12 version 005010, CORE v5010 Master Companion Guide Template, 005010, 1.2, (CORE v 5010 Master Companion Guide Template, 005010, 1.2), March 2011, as referenced in §§162.1203, 162.1403, and 162.1603.

(3) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase II Policies and Operating Rules, Approved July 2008, v5010 Update March 2011.

(i) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, as referenced in § 162.1403.

(ii) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(v) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011, as referenced in § 162.1203 and § 162.1403.

(4) Council for Affordable Quality Healthcare (CAQH) Phase III Committee on Operating Rules for Information Exchange (CORE) EFT & ERA Operating Rule Set, Approved June 2012, as specified in this paragraph and referenced in § 162.1603.

(i) Phase III CORE 380 EFT Enrollment Data Rule, version 3.0.0, June 2012.

(ii) Phase III CORE 382 ERA Enrollment Data Rule, version 3.0.0, June 2012.

(iii) Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, version 3.0.0, June 2012.

(iv) CORE-required Code Combinations for CORE-defined Business Scenarios for the Phase III CORE 360 Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule, version 3.0.0, June 2012.

(v) Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule, version 3.0.0, June 2012.

(vi) Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012, except Requirement 4.2 titled “Health Care Claim Payment/Advice Batch Acknowledgement Requirements”.

(d) The National Automated Clearing House Association (NACHA), The Electronic Payments Association, 1350 Sunrise Valley Drive, Suite 100, Herndon, Virginia 20171 (Phone) (703) 561-1100; (Fax) (703) 713-1641; Email: info@nacha.org; and Internet at <http://www.nacha.org>. The implementation specifications are as follows:

(1) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules, Appendix One: ACH File Exchange Specifications (Operating Rule 59) as referenced in § 162.1602.

(2) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules Appendix Three: ACH Record Format Specifications (Operating Rule 78), Part 3.1, Subpart 3.1.8 Sequence of Records for CCD Entries as referenced in § 162.1602.

[68 FR 8396, Feb. 20, 2003, as amended at 69 FR 18803, Apr. 9, 2004; 74 FR 3324, Jan. 16, 2009; 76 FR 40495, July 8, 2011; 77 FR 1590, Jan. 10, 2012; 77 FR 48043, Aug. 10, 2012]

§ 162.923 Requirements for covered entities.

(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts, with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

(b) *Exception for direct data entry transactions.* A health care provider electing to use direct data entry offered by a health plan to conduct a transaction for which a standard has been adopted under this part must use the applicable data content and data condition requirements of the standard when conducting the transaction. The health care provider is not required to use the format requirements of the standard.

(c) *Use of a business associate.* A covered entity may use a business associate, including a health care clearinghouse, to conduct a transaction covered by this part. If a covered entity chooses to use a business associate to conduct all or part of a transaction on behalf of the covered entity, the covered entity must require the business associate to do the following:

(1) Comply with all applicable requirements of this part.